K112790

MAY - 7 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submission correspondent:

Karen Hill
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Axis-Shield Diagnostics Ltd.
The Technology Park
Dundee
DD2 1XA,
Scotland, UK

Device Name: 3-Reagent Homocysteine Assay for SYNCHRON® and UniCel®

Reagents:

Classification Name: Urinary Homocystine (Nonquantitative) Test System

Trade Name: 3-Reagent Homocysteine Assay for SYNCHRON® and UniCel®

Common Name: Homocysteine Enzyme Assay

Governing Regulation: 862.1377

Device Classification: Class II

Classification Panel: Clinical Chemistry

Product Code: LPS

Legally marketed device to which equivalency is claimed:

Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent (k083222)

Intended Use of Device:

The 3-Reagent Homocysteine Assay for Beckman Coulter SYNCHRON® and UniCel® systems is intended for in vitro quantitative determination of total homocysteine in human serum and plasma. The device can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

Description of Device:

Bound or dimerised homocysteine (oxidised form) is reduced to free homocysteine, which then reacts with serine catalysed by cystathionine beta-synthase (CBS) to form cystathionine. Cystathionine in turn is broken down by cystathionine beta-lyase (CBL) to form homocysteine, pyruvate and ammonia. Pyruvate is then converted by lactate dehydrogenase (LDH) to lactate with nicotinamide adenine dinucleotide (NADH) as coenzyme. The rate of NADH conversion to NAD+ is directly proportional to the concentration of homocysteine (Δ A340 nm).

Comparison of Technological Characteristics:

The 3-Reagent Homocysteine Assay for SYNCHRON® and UniCel® and the Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent are both enzymatic assays for the quantitative determination of total homocysteine in human serum and plasma. The calibrator formulations are identical and although both assays use the same cycling enzyme assay technology, the number or reagents and reagent formulations are different.

Summary of Non-Clinical Performance:

The 3-Reagent Homocysteine Assay for SYNCHRON® and UniCel® is substantially equivalent to the Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent in terms of precision, calibration, limit of detection and linearity on dilution as demonstrated in non-clinical performance data in this 510(k) submission.

Summary of Clinical Performance:

The 3-Reagent Homocysteine Assay for SYNCHRON® and UniCel® demonstrated substantially equivalent performance to the Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent as indicated by a method comparison study, in which a Passing & Bablock method comparison and a Pearson correlation analysis was conducted using 100 samples covering the full measuring range of the assay.

The 3-Reagent Homocysteine Assay for SYNCHRON® and UniCel® on the Synchron LX Pro analyzer demonstrated substantially equivalent performance to the Axis-Shield

Liquid Stable (LS) 2-Part Homocysteine Reagent on the Olympus AU400 analyser as indicated by a slope of 1.01 (95% CI: 0.99 to 1.04), an intercept of 0.07 (95% CI: -0.30 to 0.44) and a correlation coefficient (r) of 0.997 (95% CI: 0.99 to 1.00).

The 3-Reagent Homocysteine Assay for SYNCHRON® and UniCel® on the Unicel DxC analyzer demonstrated substantially equivalent performance to the Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent on the Olympus AU400 analyser as indicated by a slope of 0.99 (95% CI: 0.97 to 1.02), an intercept of 0.74 (95% CI: 0.30 to 1.11) and a correlation coefficient (r) of 0.994 (95% CI: 0.99 to 1.00).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Axis-Shield Diagnostics Ltd.
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The Technology Park
Luna Place
Dundee, UK, DD2 1XA, UK

MAY - 7 2012

Re: k112790
Trade/Device Name: 3-Reagent Homocysteine Assay for Synchron® and Unicel®
Regulation Number: 21 CFR § 862.1377
Regulation Name: Urinary Homocysteine (Nonquantitative) Test System
Regulatory Class: Class II
Product Code: LPS
Dated: March 30, 2012
Received: April 3, 2012

Dear Karen Hill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: K112790

3-Reagent Homocysteine Assay for SYNCHRON® and Unicel®

Indication For Use:

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Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112790